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10/588,489	08/04/2006	Eric Perouse	2006_1244A	6680

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EXAMINER

TANNER, JOCELIN C

ART UNIT	PAPER NUMBER
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3731

NOTIFICATION DATE	DELIVERY MODE
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04/28/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/588,489	Applicant(s) PEROUSE, ERIC	
	Examiner JOCELIN C. TANNER	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/15/2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is in response to the Amendment filed 15 January 2010. Claims 25-44 are currently pending. The Examiner acknowledges the amendments to claims 25, 30, 36 and 41.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. **Claims 25-32, 34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berg et al. (US Patent No. 6,451,048) in view of Goldsteen et al. (US Patent No. 5,976,178) and further in view of Berg et al. (US Patent No. 6,994,713).**

3. Regarding claim **25**, Berg et al. discloses a deformable lattice (30) including a silicone covering coating crossed nitinol wire arranged to define meshes, connectors (34) including two external hooks having hook portions (52, Fig. 6a) that are capable of defining a clamp for anchoring the prosthesis to tissue, at least two hooks formed of flexible nitinol material and mounted to the lattice at opposite sides of one of the meshes (Fig. 3), the hooks being capable of moving from a spaced apart position such that the clamp is open and a close-together position wherein the clamp is closed (Figs. 10a, 10b). However, Berg et al. fails to expressly disclose the lattice having a retracted state wherein the lattice has a small diameter and expanded state wherein the lattice has a larger diameter such that the meshes are capable of having a first shape when

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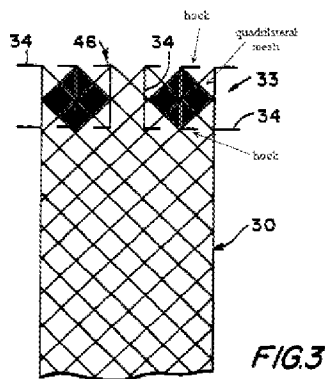
the lattice is contracted such that the hooks are spread apart and a second shape when the lattice is expanded such that the at least two hooks of the clamp are in a close-together position.

Goldsteen et al. teaches tubular member formed of a nitinol frame (432) and a coating of a highly elastic material, i.e. silicone, the tubular member including a radially compressed configuration and a radially expanded configuration, wherein the meshes are compressed and expanded within the lattice thus being capable of opening and closing the clamps of Berg et al. (column 3, lines 8-35, column 12, lines 26-47, Fig. 16).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the device of Berg et al. with means to expand and compress, as taught by Goldsteen et al., to allow the lattice to stay open and be distensible so that it may pulsate like natural circulatory system tubing in response to pressure waves in the blood flow (column 12, lines 40-45).

Berg et al. ('713) teaches a graft connector having a medial portion (16) therebetween axially extending fingers (14) wherein the free ends of the fingers overlap when the graft is installed within a patient (column 9, lines 1-9, Fig. 17).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the device of the combination of Berg et al. and Goldsteen et al. with overlapping hooks, as taught by Berg et al. ('713), to help increase the contact area between the hooks and the tissue between them and the compression of the tissue between the fingers (column 9, lines 5-8).



4. Regarding claim **26**, the combination of Berg et al. ('048), Goldsteen et al. and Berg et al. ('713) discloses at least two hooks having a connection end that is connected to the lattice and capable of moving relative to each other during deformation of the lattice from a retracted to an expanded configuration.
5. Regarding claim **27**, Berg et al. ('048) discloses meshes of a lattice having a shape of a deformable quadrilateral wherein the at least two hooks are connected to the lattice at a respective corner of the meshes. Please see figure above.
6. Regarding claim **28**, Berg et al. ('048) discloses the connection end of the hooks may be attached to the lattice by welding (column 5, lines 23-25).
7. Regarding claim **29**, Berg et al. ('048) discloses at least two hooks having a strand twisted connection end to the lattice (column 5, lines 1-20).
8. Regarding claim **30**, the combination of Berg et al. ('048), Goldsteen et al. and Berg et al. ('713) discloses crook portions of at least two hooks (Fig. 6a, Berg et al. ('048)) and at least two hooks that are shaped and arranged to at least partly overlap when the lattice is in an expanded state so as to form a clamp (Fig. 17, Berg et al. ('713)).

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9. Regarding claim **31**, the combination of Berg et al. ('048), Goldsteen et al. and Berg et al. ('713) discloses that each hook may be in the form of a substantially rectilinear blade, the two hooks extending facing each other and spaced apart from each other when the clamp is open and the lattice is in an expanded state (Figs. 3, 7b, Berg et al. ('048), Fig. 17, Berg et al. '713).

10. Regarding claim **32**, Goldsteen et al. discloses a lattice that is elastically deformable towards an expanded position (column 12, lines 40-45).

11. Regarding claim **34**, Berg et al. ('048) discloses a lattice having a tubular shape and at least two hooks (3310) that are offset circumferentially with respect to each other around the tubular prosthesis (3300) (Fig. 33).

12. Regarding claim **35**, Berg et al. discloses two hooks that are offset circumferentially by a first circumferential spacing with respect to each other around the tubular shaped lattice when the hooks are in a spaced-apart position (Fig. 3), the at least two hooks are offset circumferentially by a second circumferential spacing when the two hooks are in a close-together position that is smaller than the first circumferential spacing (Figs. 17, Berg et al. ('713)).

13. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Berg et al. (US Patent No. 6,451,048) in view of Goldsteen et al. (US Patent No. 5,976,178) and further in view of Berg et al. (US Patent No. 6,994,713), as applied to claim 25 above, and further in view of Schwartz et al. (US Patent No. 5,443,496).

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14. Regarding claim **33**, the combination of Berg et al. ('048), Goldsteen et al. and Berg et al. ('713) discloses all of the limitations previously discussed except for a stretchable liquid-proof film.

Schwartz et al. teaches a lattice formed of wire having a polyurethane film disposed thereon wherein the film is capable of stretching to preserve the radial expandability and axial flexibility of the lattice (column 4, lines 11-34).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the lattice of the combination of Berg et al. ('048), Goldsteen et al. and Berg et al. ('713) with the stretchable polyurethane film, as taught by Schwartz et al., to provide a biocompatible polymeric surface to contact and support a body lumen and to preserve the radial expandability and axial flexibility of the lattice (column 4, lines 11-34).

15. Claims 36-42 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berg et al. (US Patent No. 6,451,048) in view of Goldsteen et al. (US Patent No. 5,976,178) and further in view of Berg et al. (US Patent No. 6,994,713) in view of Perez et al. (US Patent No. 6,984,244).

16. Regarding claim **36**, Berg et al. discloses a deformable lattice (30) including a silicone covering coating crossed nitinol wire arranged to define meshes, connectors (34) including two external hooks having hook portions (52, Fig. 6a) that are capable of defining a clamp for anchoring the prosthesis to tissue, at least two hooks formed of flexible nitinol material and mounted to the lattice at opposite sides of one of the meshes (Fig. 3), the hooks being capable of moving from a spaced apart position such

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that the clamp is open and a close-together position wherein the clamp is closed (Figs. 10a, 10b). However, Berg et al. fails to expressly disclose the lattice having a retracted state wherein the lattice has a small diameter and expanded state wherein the lattice has a larger diameter such that the meshes are capable of having a first shape when the lattice is contracted such that the hooks are spread apart and a second shape when the lattice is expanded such that the at least two hooks of the clamp are in a close-together position.

Goldsteen et al. teaches tubular member formed of a nitinol frame (432) and a coating of a highly elastic material, i.e. silicone, the tubular member including a radially compressed configuration and a radially expanded configuration, wherein the meshes are compressed and expanded within the lattice thus being capable of opening and closing the clamps of Berg et al. (column 3, lines 8-35, column 12, lines 26-47, Fig. 16).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the device of Berg et al. with means to expand and compress, as taught by Goldsteen et al., to allow the lattice to stay open and be distensible so that it may pulsate like natural circulatory system tubing in response to pressure waves in the blood flow (column 12, lines 40-45).

Berg et al. ('713) teaches a graft connector having a medial portion (16) therebetween axially extending fingers (14) wherein the free ends of the fingers overlap when the graft is installed within a patient (column 9, lines 1-9, Fig. 17).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the device of the combination of Berg et

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al. and Goldsteen et al. with overlapping hooks, as taught by Berg et al. ('713), to help increase the contact area between the hooks and the tissue between them and the compression of the tissue between the fingers (column 9, lines 5-8).

Perez et al. teach a medical repair device delivery system wherein a repair device or "lattice" (390) is encompassed by a capsule or "holding means" (FIG. 12, element #333) which restrains the repair device and prevents its deployment (column 12, lines 63-64). The lattice is secured by its distal end to an inner catheter or "delivery tube" (FIG. 12, element #320) which restricts the repair device from deployment and delivers the device to the treatment site. The hooks (FIG. 2, element #96) are pressed into the grooves or "channels" (FIG. 14, element #376) arranged within the stop ring or "confinement duct" (FIG. 12, element #370) of a lattice delivery tube that is attached to the distal end of the inner catheter. The holding means prevents the hooks from contacting the sheath assembly (column 12, lines 65-68, FIG. 13, element #340). The hooks are free to embed in the vasculature once the capsule and sheath assembly are retracted (column 13, lines 12-13, column 14, lines 15-36).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a retaining device for holding the lattice of the combination of Berg et al. ('048), Goldsteen et al. and Berg et al. ('713) in a retracted state, as taught by Perez et al., for the predictable result of preventing the hooks from piercing the tissue prior to installation.

17. Regarding claim **37**, Perez et al. discloses longitudinal grooves wherein hooks are disposed therein (column 13, lines 40-46).

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18. Regarding claim **38**, the combination of Berg et al. ('048), Goldsteen et al. and Berg et al. ('713) discloses at least two hooks having a connection end that is connected to the lattice and capable of moving relative to each other during deformation of the lattice from a retracted to an expanded configuration.

19. Regarding claim **39**, Berg et al. ('048) discloses meshes of a lattice having a shape of a deformable quadrilateral wherein the at least two hooks are connected to the lattice at a respective corner of the meshes. Please see figure above.

20. Regarding claim **40**, Berg et al. ('048) discloses the connection end of the hooks may be attached to the lattice by welding (column 5, lines 23-25).

21. Regarding claim **41**, the combination of Berg et al. ('048), Goldsteen et al. and Berg et al. ('713) discloses crook portions of at least two hooks (Fig. 6a, Berg et al. ('048)) and at least two hooks that are shaped and arranged to at least partly overlap when the lattice is in an expanded state so as to form a clamp (Fig. 17, Berg et al. ('713)).

22. Regarding claim **42**, the combination of Berg et al. ('048), Goldsteen et al. and Berg et al. ('713) discloses that each hook may be in the form of a substantially rectilinear blade, the two hooks extending facing each other and spaced apart from each other when the clamp is open and the lattice is in an expanded state (Figs. 3, 7b, Berg et al. ('048), Fig. 17, Berg et al. '713).

23. Regarding claim **44**, Berg et al. ('048) discloses a lattice having a tubular shape and at least two hooks (3310) that are offset circumferentially with respect to each other around the tubular prosthesis (3300) (Fig. 33).

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24. Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over Berg et al. (US Patent No. 6,451,048) in view of Goldsteen et al. (US Patent No. 5,976,178) and further in view of Berg et al. (US Patent No. 6,994,713) in view of Perez et al. (US Patent No. 6,984,244), as applied to claim 36 above, and further in view of Schwartz et al. (US Patent No. 5,443,496).

25. Regarding claim **43**, the combination of the combination of Berg et al. ('048), Goldsteen et al., Berg et al. ('713) and Perez et al. discloses all of the limitations previously discussed except for a stretchable liquid-proof film.

Schwartz et al. teaches a lattice formed of wire having a polyurethane film disposed thereon wherein the film is capable of stretching to preserve the radial expandability and axial flexibility of the lattice (column 4, lines 11-34).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the lattice of the combination of Berg et al. ('048), Goldsteen et al., Berg et al. ('713) and Perez et al. with the stretchable polyurethane film, as taught by Schwartz et al., to provide a biocompatible polymeric surface to contact and support a body lumen and to preserve the radial expandability and axial flexibility of the lattice (column 4, lines 11-34).

Response to Arguments

26. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

27. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOCELIN C. TANNER whose telephone number is (571)270-5202. The examiner can normally be reached on Monday through Thursday between 9am and 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jocelin C. Tanner/
4/20/2010
Examiner, Art Unit 3731

/Anh Tuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731
4/25/10